REMARKS

The present application relates to hybrid maize plant and seed 34B97. Claims 55, 58, 59, 64, and 65 have been canceled. Claims 8, 44-51, and 63 have been amended. Claim 66 has been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Status of the Application

Applicant acknowledges the rejections of claims 6, 11, 15, 19, 21, 24, 28, and 32-34 under 35 U.S.C. § 112, second paragraph, as withdrawn. The rejection of claims 11, 15, 19, 24, 28, 32, 40, and 41 under 35 U.S.C. § 112, first paragraph, are also acknowledged as withdrawn.

B. Specification

Applicant submits the Deposit section on page 48 has been amended in order to properly include both the hybrid maize plant 34B97 and the inbred parents GE533003 and GE567919 within the Deposit paragraph. The changes do not add new matter as there is literal support for the minor changes on pages 7 in the originally filed specification. The specification has now been amended to correct these minor changes.

In addition, Applicant respectfully submits that the actual ATCC deposit of the two inbred plants will be delayed until the receipt of notice that the application is otherwise in condition for allowance, in compliance under 37 C.F.R. §§ 1.801-1.809. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination and the name and address of the depository. The claims will also be amended to recite the ATCC deposit number. Applicant submits that at least 2,500 seeds of hybrid maize plant 34B97 and the inbred parents GE533003 and GE567919 will be deposited with the ATCC. Applicant further asserts that the deposits will be made without restriction.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 8 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record stated in the Office Action mailed December 11, 2002.

Applicant traverses this rejection. Applicant has now amended claim 8 to delete the terminology "has been manipulated to be male sterile" and include the recitation --an introgressed cytoplasmic gene that confers male sterility--, thus alleviating this rejection.

Claims 45-51, 59, and 64 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 45 and 49 stand rejected for the recitation "value added trait gene" as rendering the claims indefinite. In addition, the Examiner states there is improper antecedent basis.

Applicant has amended claims 45 and 49 to delete the terminology "value added trait gene" and included the recitation -- a gene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism--. Applicant notes this is terminology used by Supervisory Patent Examiner (SPE) Amy Nelson and Examiner David Fox in the faxed proposed claims 17 and 19 of November 15, 2002, thereby alleviating this rejection.

The Examiner rejects claims 46 and 50 for the recitation "derivative or a synthetic polypeptide modeled thereto" as indefinite.

Applicant has amended claims 46 and 50 to delete the rejected language and include --endotoxin--, as suggested by the Examiner, alleviating this rejection.

Claim 48 is indefinite as the Examiner states the last line of the claim is not consistent with the preamble.

Applicant has amended claim 48 to make the last line of the claim consistent with the preamble thereby deleting "transgenic" and inserting --backcross conversion--, as suggested by the Examiner, thus alleviating this rejection.

The Examiner rejects claim 59 for the recitation "genetic identity" as indefinite.

Applicant has now canceled claim 59, thereby alleviating this rejection.

Claim 64 stands rejected as indefinite as the Examiner states it does not recite any positive method steps.

Applicant has canceled claim 64, alleviating this rejection.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 44, 48-51, 55, and 58-65 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed December 11, 2002.

Applicant traverses this rejection. Applicant has canceled claims 55, 58, 59, 64, and 65, thus alleviating this rejection. Claims 44-51 and 63 have been amended. Applicant has amended the claims to be in the format indicated as allowable by the claims faxed by SPE Amy Nelson and Examiner David Fox. Further, claim 60 is a method claim that is adequately described in the specification on page 5, first full paragraph, thereby alleviating this rejection. Applicant asserts, as stated in the written description guidelines, an old process performed with a novel material is novel in and of itself. 66 Federal Register 1099, Vol. 66, No. 4 (January 5, 2001). Thus claims 61-63 are methods patentable pursuant to the written description guidelines. See Example 10, Revised Interim Written Description Guidelines Training Materials, in which claim 1 therein is indicated as allowable. Applicant respectfully submits the claims now come within the purview of the written description requirement and request reconsideration.

Claims 44-51, 56, 57, and 59 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office Action mailed December 11, 2002.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 34B97 and the

inbred parents GE533003 and GE567919 within the Deposit paragraph on page 48. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The specification has now been amended to correct these minor changes. Applicant thanks the Examiner for pointing out this inadvertent mistake.

In addition Applicant submits that the actual ATCC deposit will be delayed until receipt of notice that the application is otherwise in condition for allowance. As provided in 37 C.F.R. §§ 1.801-1.809, Applicant wishes to reiterate they will refrain from deposit of hybrid 34B97 <u>and</u> inbred parents GE533003 and GE567919 until allowable subject matter is indicated. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, description of the deposited biological materials sufficient to specifically identify and to permit examination and the name and address of the depository. The claims will also be amended to recite the proper ATCC deposit numbers. The Applicant provides assurance that:

a) during the pendency of this application access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit will be maintained in a public depository for a period of thirty years, or five years after the last request for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of deposit will be conducted (see 37 C.F.R. § 1.807); and

e) the deposit will be replaced if it should ever become inviable.

Therefore, Applicant submits that at least 2500 seeds of hybrid maize plant 34B97 and the inbred parents GE533003 and GE567919 will be deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed (MPEP § 2411.02). Such action is respectfully requested.

Claims 48-51 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The Examiner states the specification does not teach inbred plants GE533003 or GE567919 comprising only a single gene that has been introduced by backcrosses. The Examiner further states it is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. The Examiner also asserts that Hunsperger *et al.*, Kraft *et al.*, and Eshed *et al.* teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype is said different plant.

Applicant respectfully traverses this rejection. Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. As stated in Poehlman *et al.* (1995) on page 334, submitted in the Information Disclosure Statement, "a backcross derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Applicants further point out that cytoplasmic male sterility genes do not introduce linked nuclear genes. Wych (1988) on page 585-586, submitted in the Information Disclosure Statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile inbred to be the same variety as the F1 hybrid produced with the fertile version of the inbred. Applicants also refer the Examiner to Openshaw *et al.* submitted herewith as Appendix A, which states the "the backcross breeding procedure is being used widely to transfer simply inherited traits into elite genotypes...Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm."

The Examiner has cited Hunsperger, Kraft, and Eshed *et al.* and stated that they "teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant." The Examiner states that, "Hunsperger *et al.* teaches that the introgession of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait" (column 3, lines 26-46). Applicant respectfully disagrees that this is what is taught by Hunsperger *et al.* Hunsperger *et al.* merely teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger *et al.* merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger *et al.* succeeded in incorporating the gene into petunia plants of different genetic backgrounds. In fact, the USPTO in Hunsperger *et al.* allowed claims to any petunia plant comprising genes for dwarfism. Therefore, Hunsperger *et al.* supports the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as hybrid maize seed 34B97 and inbred parents GE533003 and GE567919, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer *et al.* relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft *et al.* teaches that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature" (page 323, column 1, lines 7-15). Applicant disagrees that the article states such points. Kraft *et al.* makes no mention of a plant comprising a single gene conversion or the use of backcrossing. Further, Kraft *et al.* relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft *et al.* states, on page 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, <u>backcrossing</u>, or <u>transformation</u> by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix B.

The Examiner goes on to state that, "Eshed *et al.* teaches that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in genetically complex and less than additive fashion" (page 1815, column 1, line 1 to page 1816, column 1, line 1). The Applicant would like to point out on page 1816, column 1, lines 1-5 of the Eshed *et al.* article it states, "Recent studies that detected epistasis of selected QTL in Drosophila (Long et al. 1995), soybean (Lark *et al.* 1995) and <u>maize</u> (Doebley *et al.* 1995; Cockerham and Zeng 1996) did <u>not</u> show a less-than-additive trend." Emphasis added. Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Claims 44-51 have been amended to expedite prosecution. In claims 44-51, the genes transferred into 34B97 are now limited to the traits of disease resistance, insect resistance, herbicide resistance, male sterility, and a gene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism. Applicant respectfully requests Examiner to withdraw this rejection.

Claims 58 and 59 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that double haploid methods are not taught by the specification.

Applicant traverses this rejection. In an effort to expedite prosecution claims 58 and 59 have been canceled making the rejection moot.

Applicant would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

Applicants have also added claim 66 to further describe the line produced in such a manner by traits that do not vary from the deposited line at a 5% significance level when measured in the same environmental conditions. Phenotypic traits, an identifying characteristic, are a method utilized by those of ordinary skill in the art to compare two lines, and are the method used by the patent office to evaluate the novelty of the deposited line itself. One of ordinary skill in the art of plant breeding would know how to evaluate the traits of two plant varieties to determine if there is no statistically significant variation when determined, for example, at a 5% significance level and when grown in the same environmental conditions between the traits expressed by those varieties. For the reasons aforementioned, it is respectfully submitted that Applicants' claims are sufficiently described and enabled by the specification.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 44-51 and 55-65 under 35 U.S.C. § 112, first paragraph.

Summary

Applicant acknowledges that claims 1-7, 20, 52, 53, and 54 are allowed.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Marker-assisted Selection in Backcross Breeding

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Abstract. **The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Genetic markers can increase the effectiveness of backcrossing by 1) increasing the probability of obtaining a suitable conversion, and 2) decreasing the time required to achieve an acceptable recovery. Simulation and field results indicated that, for a genome consisting of ten 200-cM chromosomes, basing selection on 40 or 80 markers in 50 BC individuals that carry the allele being transferred can reduce the number of backcross generations needed from about seven to three.**

The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Usually, the trait being transferred is controlled by a single gene, but highly heritable traits that are more complexly inherited have also been transferred successfully by backcrossing; for example, maturity in maize (Rinke and Sentz, 1961; Shaver, 1976). Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm.

Several plant breeding textbooks give good descriptions of the backcross procedure (Allard, 1960; Fehr, 1987). A donor parent (DP) carrying a trait of interest is crossed to the recurrent parent (RP), an elite line that is lacking the trait. The F_1 is crossed back to the RP to produce the BC_1 generation. In the BC_1 and subsequent backcross generations, selected individuals carrying the gene being transferred are backcrossed to the RP. The expected proportion of DP genome is reduced by half with each generation of backcrossing. Ignoring effects of linkage to the selected DP allele being transferred, the percentage recurrent parent (%RP) genome expected in each backcross generation is calculated as:

$$\%RP = 100\,[1 - (0.5)^{n+1}]$$

where n is the number of backcrosses.

Backcrossing of selected plants to the RP can be repeated each cycle until a line is obtained that is essentially a version of the RP that includes the introgressed allele. After six backcrosses, the expected recovery is >99% (Table 1).

Until recently, discussions of the recovery of the RP genome during backcrossing have emphasized the expected values for %RP shown in Table 1, and have largely ignored the genetic variation for %RP that exists around the expected mean. With the development of genetic markers capable of providing good genome coverage, there has been interest in taking advantage of that variation to increase the efficiency of backcrossing.

Selection for RP marker alleles can increase greatly the effectiveness of backcross programs by allowing the breeder to 1) select backcross plants that have a higher proportion of RP genome, and 2) select backcross individuals that are better conversions near a mapped donor allele being transferred (i.e., select for less linkage drag). Expressed in practical terms, using genetic markers to assist backcrossing can 1) increase the probability of obtaining a suitable conversion, and 2) decrease the time required to achieve an acceptable recovery.

Issues to consider when planning a marker-assisted backcross program include 1) the time advantage of using markers to assist backcrossing, 2) the number of markers needed, and 3) the number of genotypes to evaluate. In this report, we use results from previous literature, computer simulation, and empirical studies to provide some guidelines.

Table 1. *Expected recovery of recurrent parent (RP) genome during backcrossing, assuming no linkage to the gene being transferred.*

Generation	%RP
F_1	50.0000
BC_1	75.0000
BC_2	87.5000
BC_3	93.7500
BC_4	96.8750
BC_5	98.4375
BC_6	99.2188
BC_7	99.6094

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Appendix A
Serial No. 09/759,790

Materials and methods

The maize genome was the model for the simulation. The simulated genome contained ten 200-cM chromosomes. Simulation of crossing over was based on a Poisson distribution with a mean of 2.0 ($\lambda = 2$) (Hanson, 1959), which, on average, generated one cross over for every 100-cM length. The simulations reported here assume no interference. Codominant genetic markers were evenly distributed in the genome and sites of the donor gene were randomly assigned to genome locations.

Simulations were conducted with the following parameters:

Number of progeny: 100 or 500.
Backcross generations: BC_1, BC_2, and BC_3.
Number of markers: 20, 40, 80, or 100.
Number selected to form the next BC generation: 1 or 5.

Selection was based on 1) presence of the donor allele and 2) high %RP). %RP was calculated as the average of the (one or five) selected individuals. Values presented are the mean of 50 simulations.

Results

In the computer simulation study, all methods modeled greatly increased the speed of recovering the RP genome compared to the expected recovery with no marker-assisted selection (compare Tables 1 and 2). At least 80 markers were required to recover 99% of the RP genome in just three BC generations (Table 2). Use of at least 80 markers and 500 progeny allowed recovery of 98% RP in just two BC generations. Response to selection was diminished only slightly by spreading the effort over five selections. Using markers, the number of backcross generations needed to convert an inbred is reduced from about seven to three.

By the BC_3 generation, there appears to be no practical advantage to using 500 vs. 100 individuals. If th presence of the donor trait in the backcross individuals can be ascertained before markers are genotyped, then only half the number of individuals indicated in the tables will need to be analyzed.

When a small number of markers are used, they quickly became non-informative; i.e., selection causes the marker loci to became fixed for the RP type before the rest of the genome is fully converted (Table 3; Hospital et al., 1992). This situation was most prominent in the larger populations, where a higher selection intensity placed more selection pressure upon the marker loci. Accordingly, it is of interest to consider how closely the estimation of %RP based on markers reflects the actual genome composition. The combination of estimation of %RP based on fewer markers and subsequent selection tends to bias the estimates upward (compare Tables 2 and 3).

The results from the simulation compare well with real field data. In a typical example, 50 BC_1 plants carrying the gene being transferred were genotyped at 83 polymorphic RFLP loci (note that this corresponds to a population size of 100 unselected plants in Tables 2 and 3). The five best BC_1 recoveries had estimated %RP values of 85.9%, 82.7%, 82.0%, 81.4%, and 81.2%. After evaluating 10 BC_2 plants from each selected BC_1, the best BC_2 recovery had an estimated %RP of 94.6%.

Discussion

The simulations (Table 2; Hospital et al., 1992) and our experience indicate that four markers per 200-cM chromosome is adequate to greatly increase the effectiveness of selection in the BC_1. However, using only four markers per 200 cM will likely make it very difficult to map the location of the gene of interest. Adequate summarization of the data is an important

Table 2. *Percent recurrent parent genome during marker-assisted backcrossing.*

	100 Progeny				500 Progeny			
	No. markers				No. markers			
Generation	20	40	80	100	20	40	80	100
				One selected				
BC_1	84.5	84.5	84.2	88.0	89.9	90.7	90.2	90.5
BC_2	95.0	95.2	95.8	97.2	96.5	97.7	98.5	98.6
BC_3	97.4	97.6	98.9	99.2	97.7	98.3	99.4	99.5
				Five selected				
BC_1	82.9	85.1	84.9	84.7	87.7	88.1	88.9	88.9
BC_2	93.7	95.0	95.8	95.7	95.5	96.8	97.8	97.9
BC_3	97.1	98.3	98.8	98.9	97.3	98.5	99.3	99.3

Table 3. *Estimates of percent recurrent parent genome, based on marker loci.*

	100 Progeny				500 Progeny			
	No. markers				No. markers			
Generation	20	40	80	100	20	40	80	100
				One selected				
BC_2	98.7	97.8	95.6	97.2	100.0	99.1	98.6	98.0
BC_3	100.0	99.8	99.3	99.5	100.0	100.0	99.9	98.2
				Five selected				
BC_2	96.4	96.5	96.2	95.8	100.0	98.5	98.3	98.2
BC_3	99.9	99.8	99.3	99.1	100.0	100.0	99.9	99.8

part of a marker-assisted backcross program. Ideally, the markers used can supply data that can be represented as alleles of loci with known map position. Estimation of %RP, mapping the position of the locus of interest, and graphical display of the results (Young and Tanksley, 1989) are all useful in understanding and controlling the specific backcross experiment being conducted.

It appears that, with the use of genetic markers, the portion of the RP genome that is not linked to the allele being transferred can be recovered quickly and with confidence. The recovery of RP will be slower on the chromosome carrying the gene of interest. A considerable amount of linkage drag is expected to accompany selection for the DP allele in a backcross program. For a locus located in the middle of a 200-cM chromosome, the length of the DP chromosome segment accompanying selection is expected to be 126, 63, and 28 cM in the BC_1, BC_3, and BC_7 generations, respectively (Hanson, 1959; Naveira and Barbadilla, 1992). Our observations support the recommendation of Hospital et al. (1992) that preference be given to the selection for recombinants proximal to the allele of interest, but that selection for recovery of the RP elsewhere in the genome also be considered. This two-stage selection can probably be done quite effectively ad hoc by the breeder once the data is adequately summarized; however, Hospital et al. suggest ways to incorporate the two criteria into a selection index such that each component of selection is assured appropriate weighting.

Use of genetic markers can greatly increase the effectiveness of backcrossing, and they should be used in any serious backcrossing program if resources are available to the breeder.

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What is an "Essentially Derived Variety"?

The concept of essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents, gap which was becoming important due to the development of the use of patented genetic traits in genetic engineering.

An essentially derived variety is a variety which is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety.

As indicated as an example in the UPOV Convention, essentially derived varieties may be obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

The commercialization of an essentially derived variety needs the authorization of the owner of the rights vested in the initial variety.

The concept of essentially derived variety does not at all abolish the Breeder's Exemption, as free access to protected plant varieties for breeding purposes is maintained. It is not a threat to biodiversity. On the contrary, it favors biodiversity, encouraging breeders developing and marketing original varieties.

Appendix B
Serial No. 09/759,790

www. upov. org

INTERNATIONAL CONVENTION

FOR THE

PROTECTION OF NEW VARIETIES OF PLANTS

of December 2, 1961, as revised
at Geneva on November 10, 1972,
on October 23, 1978, and
on March 19, 1991

adopted by the Diplomatic Conference

on March 19, 1991

reproduced from UPOV Publication No. 438(E)
issue No. 63 of "Plant Variety Protection"

Article 12
Examination of the Application

Any decision to grant a breeder's right shall require an xamination for compliance with the conditions under Articles 5 to 9. In the course of the examination, the authority may grow the variety or carry out other necessary tests, cause the growing of the variety or the carrying out of other necessary tests, or take into account the results of growing tests or other trials which have already been carried out. For the purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material.

Article 13
Provisional Protection

Each Contracting Party shall provide measures designed to safeguard the interests of the breeder during the period between the filing or the publication of the application for the grant of a breeder's right and the grant of that right. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorization as provided in Article 14. A Contracting Party may provide that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application.

CHAPTER V
THE RIGHTS OF THE BREEDER

Article 14
Scope of the Breeder's Right

(1) [Acts in respect of the propagating material] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

(i) production or reproduction (multiplication),

(ii) conditioning for the purpose of propagation,

(iii) offering for sale,

(iv) selling or other marketing,

(v) exporting,

(vi) importing,

(vii) stocking for any of the purposes mentioned in (i) to (vi), above.

(b) The breeder may make his authorization subject to conditions and limitations.

(2) [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

(3) [Acts in respect of certain products] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested mat rial.

(4) [Possible additional acts] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.

(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected variety.

(b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

Article 15
Exceptions to the Breeder's Right

(1) [Compulsory exceptions] The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

(2) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting,